REMARKS

The Office Action of May 21, 2003 has been received and reviewed. Claims 1, 3, 5-7, 11, 13, 14, 73-86 and 96-105 are pending in the application. Claims 1, 3, 5-7, 11, 13, 14, 73-86, 96, 97, 99 and 105 stand rejected, claims 103 and 104 were withdrawn from consideration, and claims 98 and 100-102 stand allowed. Claim 1 has been amended and new claims 106 and 107 have been added as set forth herein. All amendments are made without prejudice or disclaimer. Reconsideration is respectfully requested.

Applicants would like the Examiner and the Examiner's supervisor for the courtesy extended in the interview on August 13, 2003.

Specification

During the interview, the applicants' attorneys agreed to review the specification in order to ensure that the sequence rules are complied with. After review of the specification, the applicants note that a substitute specification was filed on November 2, 2001 which should place the application in compliance with the sequence rules.

Claims 103 and 104

As discussed during the interview, the Examiner indicated that claims 103 and 104 would be entered. Claims 103 and 104 do not require a further search since independent claims 1 and 6 each include that the eukaryotic cell have a nucleic acid sequence "encoding at least one adenoviral E1 protein." Thus, claims 1 and 6 should include any and all E1 proteins including E1A and E1B as recited in claims 103 and 104.

Claims 106 and 107

New claims 106 and 107 have been added as set forth herein. Claims 106 and 107 are directed to the production of an immunoglobulin and are supported in the specification at Example 23. (*See*, Specification, Example 23, pages 58-59) Applicants respectfully submit that no new matter has been added.

Rejections under 35 U.S.C. § 112, first paragraph

Claims 77-86

Claims 77-86 stand rejected under 35 U.S.C. § 112, first paragraph, as assertedly failing to comply with the enablement requirement. Applicants respectfully traverse the rejections.

During the interview, it was noted that the enablement rejections of claims 77-86 would be removed. The claims are enabled for the following reasons.

First, the structure and function of influenza proteins were well known in the art at the time of the invention. (*See*, Fields et al., Nature, 1981 Mar 19; 290(5803):213-7) (*See also*, NCBI Entrez Nucleotide accession number NC_002018). The applicants need not provide what is well known in the art. (*See,* M.P.E.P. §§ 2164.01). Since the structure of the influenza proteins is known, all that should be required is for one skilled in the art to follow the protocol presented in Example 27 of the specification to make and use the invention of claims 77-86. (*See*, Specification as-filed, pages 61-62).

The specification also discloses three working examples and no inherent difference exists between the three working examples (EPO, IgG heavy chain, and IgG light chain) and the viral proteins of claims 77-86. (*See*, Specification at Example 9, page 37 and Example 23, pages 58-59). Further, the working example of the IgG antibodies takes the form of a multimeric protein complex that is more complicated in post-translational assembly than the viral proteins asserted to be unpredictable.

Thus, claims 77-86 are enabled.

Claims 1 and 77-86

Claims 1 and 77-86 stand rejected under 35 U.S.C. § 112, first paragraph, as assertedly lacking enablement. At least partially in view of the amendment to claim 1, applicants respectfully traverse the rejections.

During the interview, it was noted that the enablement rejections for producing a proteinaceous substance other than an adenoviral protein would be removed, but that the phrase "providing said eukaryotic cell with a gene encoding a recombinant proteinaceous substance" of claim 1 was thought to lack enablement.

As previously discussed herein, the enablement rejections of claims 77-86 were removed with regard to the viral proteins. The specification further discloses working examples wherein EPO, IgG heavy chain, and IgG light chain are produced. (*See*, *Id.*) Thus, claim 1 is also enabled for producing a proteinaceous substance other than an adenoviral protein.

Regarding the phrase reciting "providing said eukaryotic cell with a gene encoding a recombinant proteinaceous substance," although applicants do not agree that claim 1 is not enabled, to expedite prosecution, the phrase has been amended to recite "introducing a gene encoding a recombinant proteinaceous substance into the eukaryotic cell." Since the introduction of a gene into a cell is well known in the art and the specification discloses a working example of transfecting a eukaryotic cell with the gene encoding the recombinant proteinaceous substance (*See*, Specification at Example 7, page 35,), claim 1 should be enabled.

During the interview, the Examiners also asked for clarification on how E1A and E1B are enabled since claim 1 recites "E1 protein." The specification discloses that PER.C6 cells are used to produce the recombinant protein substance (*See*, *Id.*) and since PER.C6 cells include E1A and E1B (*See*, *Id.* at page 8), claim 1 should be enabled.

Accordingly, reconsideration and withdrawal of the enablement rejections are requested.

Rejections under 35 U.S.C. § 102

Claims 1, 3, 5, 6, 7, 11, 13, 14, 73-76 and 96 stand rejected under 35 U.S.C. § 102(b) as assertedly being anticipated by Setoguchi et al. Applicants respectfully traverse the rejections as hereinafter set forth.

During the interview, it was noted that the anticipation rejections of claims 1, 3, 5, 6, 7, 11, 13, 14, 73-76 and 96 would be removed. The claims are not anticipated for the following reasons.

The Setoguchi et al. reference discloses the use of: Hep3b cells to produce EPO from the DNA of a replication deficient adenovirus; Cos-7 cells to produce EPO from the DNA of a replication deficient adenovirus; and 293 cells to produce replication deficient adenoviruses encoding EPO.

Claim 1 recites, in part, "providing a eukaryotic cell having a nucleic acid sequence in the eukaryotic cell's genome, said nucleic acid sequence encoding at least one adenoviral E1 protein." Claim 6 recites, in part, "wherein said human cell has in its genome a sequence encoding at least one adenoviral E1 protein."

Since the Hep3b and COS-7 cells of Setoguchi et al. do not have a nucleic acid sequence encoding at least an E1 protein present in their genome, they cannot anticipate claims 1 and 6.

Regarding the 293 cells, claim 1 recites in part "which eukaryotic cell further does not comprise a sequence encoding a structural adenoviral protein in its genome." However, the 293 cells of Setoguchi et al. contain nucleotides 1 to 4344 of the adenovirus type 5 genome. (*See*, Louis et al., *Cloning and sequencing of the cellular-viral junctions from the human adenovirus type 5 transformed 293 cell* line, 223 Virology 423 (1997)). Within this range of nucleotides, the gene for protein IX is encoded at nucleotides 3609 to 4031 (*Adenovirus type 5 left 32% of the genome (coordinates 0% to 32.39% as measured by <ad2>)*), (*See*, NCBI Entrez Nucleotide accession number X02996 (deposited April 1999)). Thus, the genome of the 293 cells encodes protein IX. Further, since protein IX is part of the adenovirus capsid important for thermostability, protein IX is a structural protein. (*See*, Ghosh-Chudbury et al., *Protein IX, a minor component of the human adenovirus capsid is essential for the packaging of full length genomes*, 6(6) EMBO J. 1733 (1987)). Therefore, the 293 cells of Setoguchi et al. do not anticipate claim 1.

With further regard to 293 cells, claim 6 recites in part "where said human cell further does **not** produce structural adenoviral proteins." (emphasis added). As used in Setoguchi et al., the 293 cells **do** produce structural adenoviral proteins. Therefore, Setoguchi et al. cannot anticipate claim 6.

CONCLUSION

In view of the foregoing amendments and remarks presented herein, the applicants respectfully submit that the claims define patentable subject matter. If questions remain after consideration of the foregoing, the Examiner is kindly requested to contact applicants' attorney at the address or telephone number given herein.

Respectfully submitted,

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